

Application No. 09/888,264  
Amendment dated October 5, 2005  
Reply to Office Action of July 26, 2005

### **REMARKS**

Applicants respectfully request entry of the amendment and reconsideration of the claims. Claims 1 and 41 have been amended to further clarify the invention. Applicants submit the amendment is supported by the specification, including for example at page 19, lines 6-11 and page 39, lines 1-12, and raises no issues of new matter. After entry of the amendment, claims 1, 28, 34-38, 41, 43, 46, 52, 53, and 74-78 will be pending.

#### **Enablement**

Claims 1, 28, 34-38, 41, 43, 46, 52, 53, and 74-78 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner acknowledges the claimed methods are enabled for methods comprising contacting a mammalian cell or tissues sample with a candidate compound *in vitro*. The Examiner, however, alleges the methods are not enabled for contacting cells or tissues *in vivo*. Applicants respectfully traverse the rejection.

Applicants contend that one of skill in the art reading this specification would be able to use a method for screening for compounds that affect mitochondrial uncoupling without undue experimentation. There are many factors to be considered in an analysis of enablement, including breadth of the claims, nature of the invention, the state of the prior art, the level of ordinary skill, level of predictability in the art, the amount of direction provided by the inventor and the existence of working examples, and the quantity of experimentation. MPEP 2164.01(a) citing *In Re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Applicants submit the specification provides enablement for claims directed to a method for screening compounds that affect mitochondrial uncoupling. The Examiner contends that Applicants' claims are not limited to contacting a cell *in vitro* and there is no guidance for how to analyze protein expression and mitochondrial membrane potential *in vivo*. Applicants respectfully traverse.

Applicants claims are directed to method for screening for compounds that affect mitochondrial uncoupling comprising contacting a mammalian cell or tissue sample with a candidate compound and analyzing an isolated contacted mammalian cell or tissue sample. Applicants submit they have enabled contacting a mammalian cell or tissue sample with a candidate compound both *in vitro* and *in vivo*. For example, the specification describes

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administering a candidate compound to a transgenic animal comprising a polynucleotide sequence encoding human OGC or a promoter for a human OGC gene linked to a reporter gene and analyzing a tissue sample from the animal (see specification at page 19, lines 6-22). In addition, methods of administering a candidate compound to a mammal and isolating a cell or tissue sample from the mammal for analysis were well known.

The Examiner alleges the specification does not provide sufficient guidance for how to analyze protein expression or mitochondrial membrane potential in a cell or tissue *in vivo*. Without acquiescing to the rejection and solely to expedite prosecution, claims 1 and 41 have been amended to clarify that protein expression and mitochondrial membrane potential is analyzed in an isolated cell or tissue sample. The amendment renders the basis of the rejection moot.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection.

#### INTERVIEW

Applicants request an interview with the Examiner. Applicants request the Examiner contact Applicants' representative upon receipt of these papers.

#### SUMMARY

In light of the forgoing Amendment and Remarks, Applicants' submit the claims are in condition for allowance. Notice of allowable claims is requested. The Examiner is invited to telephone the undersigned attorney for clarification of any of these remarks or amendments, or to otherwise speed prosecution of this case.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

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Katherine M. Kowalchuk  
Katherine M. Kowalchuk  
Reg. No.: 36,848

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